Pat Roberts

AMENDMENT NO._____ Calendar No. 1

Purpose: To establish certain practices regarding the Food and Drug Administration's guidance documents.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 2700

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. ROBERTS (for himself and Mr. ISAKSON)

Viz:

At the end, add the following:

SEC. _____. GOOD GUIDANCE PRACTICES.

(a) IN GENERAL.—Section 701(h)(1)(C) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) is amended—

(1) by moving the margin of clause (ii) 2 ems to the left; and

(2) by adding at the end the following:

"(iii) When proposing or finalizing any guidance document under this subparagraph, the Secretary shall include in

the guidance document a statement, the contents of which are committed to the discretion of the Secretary—

"(I) explaining why the interpretation or policy set forth in such guidance document is being provided in a nonbinding guidance document and not established through rulemaking; and

"(II) identifying each specific statutory provision or regulation being interpreted in the guidance document or authorizing a policy decision described in the guidance document.".

(b) EFFECTIVE DATE.—The amendment made under subsection (a)(2) shall take effect with respect to any applicable guidance documents that are issued on or after the date that is 3 months after the date of enactment of this Act.